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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/537,180	03/29/2000	Donald R. Owen	WPB40219A	6869

25944 7590 09/27/2002

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EXAMINER
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SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/537,180**

Applicant(s)  
**Owen et al.**

Examiner  
**Irene Marx**

Art Unit  
**1651**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-292 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-292 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-43 which appears drawn to a process of maintaining/restoring viability to an organ related to oxygen, classified in Class 422, subclass 82.04, for example.

II. Claim 44-48 drawn to a process of maintaining/restoring viability to an organ related to temperature, classified in Class 422, subclass 82.12, for example.

III. Claims 49-52 and 195-197 drawn to a method of perfusing an organ by controlling pressure, classified in Class 422, subclass 82.13, for example.

IV. Claims 53-55 and 198-200 drawn to a process of perfusing an organ by using sensors, classified in Class 422, subclass 62, for example.

V. Claims 56-64 drawn to a process of transporting and storing an organ, classified in Class 62, subclass 56+, for example.

VI. Claims 65-69 drawn to an apparatus for perfusing an organ having a pressure cuff, classified in Class 435, subclass 283.1+, for example.

VII. Claims 70-71 drawn to an apparatus for perfusing an organ having a stepper motor-activated cam valve, classified in Class 435, subclass 283.1+, for example.

VIII. Claim 72 drawn to an apparatus for perfusing an organ having a gravity pressure head tank, classified in Class 435, subclass 283.1+, for example.

IX. Claims 73-75 drawn to an apparatus for perfusing an organ having a heat exchanger and a controller thereof classified in Class 435, subclass 283.1+, for example

X. Claims 76-85 drawn to an apparatus for holding an organ having a portable housing and an organ supporting surface, classified in Class 62, subclass 47.1, for example

XI. Claims 86-97 drawn to a perfusion solution kit comprising two containers, nonthermic and hypothermic classified in Class 435, subclass 1.1, for example

XII. Claims 98-123 and 223 drawn to a control system and method of using for perfusing an organ, classified in Class 422, subclass 67, for example.

XIII. Claims 124-136 drawn to a recording medium to store a control program, classified in Class 422, subclass 119, for example.

XIV. Claims 137-187 drawn to a process of maintaining and restoring viability to an organ by using hypothermic conditions classified in Class 435, subclass 1.3, for example.

XV. Claims 188-192 drawn to a process of maintaining and restoring viability to an organ by using hypothermic conditions followed by a change in temperature, classified in Class 435, subclass 1.1, for example.

XVI. Claims 201-210 and 275-292 process for transporting, storing and transplanting an organ classified in Class 604, subclass 290, for example.

XVII. Claims 211-222 drawn to a perfusion solution kit comprising two containers with different solutions for hypothermic perfusion classified in Class 604, subclass 19+, for example.

XVIII. Claims 224-267 drawn to a process of maintaining or restoring viability to an organ, subjected to ischemia or hypoxia, classified in Class 435, subclass 3, for example.

XIX. Claims 268-274 drawn to a process of maintaining or restoring viability to an organ, subjected to ischemia classified in Class 435, subclass 1.2, for example.

Each of groups I-V, XIV-XVI and XVIII-XIX is directed to separate and distinct inventions, the groups are directed variously to different processes of perfusion, maintenance and transportation of organs. These methods are distinct both physically and functionally, require different process steps and produce different products.

Each of groups VI-X, XII and XIII is directed to separate and distinct inventions. The various apparatuses and devices have different structures and components serving different functions. These devices are not required one for the other.

Each of groups IX and XVII is directed to separate and distinct inventions. The kits have distinct structural and functional properties and are not required one for the other.

The numerous methods and/or apparatuses are independent each from the other since they are not disclosed as capable of use together, they have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone.

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of Group I would not necessarily anticipate or make obvious the any of the other groups.

For these reasons restriction for examination purposes is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.



Irene Marx  
Primary Examiner  
Art Unit 1651